

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**APPLICANT(S):** Salim Yusuf  
**U.S.S.N.:** - **GROUP ART UNIT:** 1614 (Presumed)  
**FILED:** Herewith **EXAMINER:** Not Yet Known  
**FOR:** METHOD OF REDUCING TYPE 2 DIABETES IN HIGH RISK PATIENTS

\*\*\*\*\*  
**CERTIFICATE OF EXPRESS MAIL**

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service in an envelope as "Express Mail Post Office to Addressee," Express Mail Label No. **EV438991310US** addressed to: **MAIL STOP PATENT APPLICATION**, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on **February 20, 2004**.

By: 

Donna R. Davis

\*\*\*\*\*  
**MAIL STOP PATENT APPLICATION**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. **LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION**

The patents, publications or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

Customer No.: 21874  
Attorney Docket No.: 57151-CON(46453)  
U.S. Serial No.: -  
Filing Date: Herewith  
Group Art Unit: 1614 (Presumed)  
Examiner: Not Yet Known

II. COPIES

- a. ☐ Submitted herewith is a legible copy of (i) each U.S and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
- b. ☒ This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior application Serial No. **10/273,814** filed on **October 17, 2002**. The following references were submitted to, and/or cited by, the Office in the prior application (s) and, therefore, are not required to be provided in this application.

III. CONCISE EXPLANATION OF THE RELEVANCE  
(check at least one box)

- a. ☒ Except as may be indicated below in (b), all of the patents, publications or other information are in the English language or were cited in an English language Search Report.
- b. ☐ A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:
- c. ☐ The following additional information is provided for the Examiner's consideration:

**FEES**

IV. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b)  
(check one box)

- a. ☒ within three months of the filing date of a national application (37 C.F.R. § 1.97(b) (1)). No fee or certification is required.
- b. ☐ within three months of the date of entry of the national stage as set forth in §1.491 in an international application (37 C.F.R. § 1.97(b) (2)). No fee or certification is required.
- c. ☐ Before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b) (3)). No fee or certification is required. In the event that a

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first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below, or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

V. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):  
(check one box)

before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c) (1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c) (2)).

- a. ☐ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).  
or  
b. ☐ See the certification below. No fee is required.

VI. STATEMENT UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby states that

- a. ☐ each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or  
b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

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Attorney Docket No.: 57151-CON(46453)  
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c. ☐ Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned certifies that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

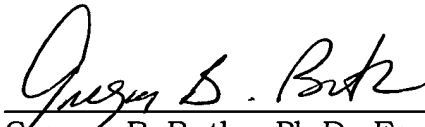
☐ Please charge Deposit Account No. 04-1105 in the amount of \$180.00 for the above-indicated fee. A triplicate copy of this paper is attached.

☒ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule, with a petition if necessary, and charge the appropriate fee to Deposit Account No. **04-1105**.

Respectfully submitted,

Date: February 20, 2004

By:   
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<b>FORM PTO-1449</b> <b>INFORMATION DISCLOSURE</b> <b>STATEMENT</b>				<b>DOCKET NO.:</b> 57151-CON(46453)		<b>SERIAL NO.:</b> -	
				<b>APPLICANT(S):</b> Salim Yusuf			
				<b>FILING DATE:</b> Herewith		<b>GROUP NO.:</b> 1614 (Presumed)	
<b>FOREIGN PATENT DOCUMENTS</b>							
		<b>DOCUMENT NUMBER</b>	<b>DATE</b>	<b>COUNTRY</b>	<b>CLASS</b>	<b>SUB- CLASS</b>	<b>TRANSLATION YES/NO</b>
	BA	WO 01/15674 A2	08/03/2001	PCT	A61K	31/00	Yes
	BB	WO 01/15673 A2	08/03/2001	PCT	A61K	31/00	Yes
	BC	DE 43 08 504 A1	22/09/1994	GERMANY	A61K	31/275	No
	BD	EP 0 331 014 A2	06/09/1989	EUROPE	A61K	37/64	No
<b>OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)</b>							
	CA	Janka, et al., "Metabolic effects of ramipril treatment in hypersensitive subjects with non-insulin-dependent diabetes mellitus," Arzneimittel-Forschung, Germany, Vol. 40, No. 4, April 1990, pp. 432-435, XP001109698.					
	CB	"Effects of ramipril on cardiovascular and microvascular outcomes in people with diabetes mellitus: results of the HOPE study and MICRO-HOPE substudy. Heart Outcomes Prevention Evaluation Study Investigators," The Lancet, England, 22 January 2000, Vol. 355, No. 9200, pp. 253-259, XP002232380.					
	CC	Krütfeldt, et al., "Ramipril increases the protein level of skeletal muscle IRS-1 and alters protein tyrosine phosphatase activity in spontaneously hypertensive rats," Naunyn-Schmiedeberg's Archives of Pharmacology, Vol. 362, No.1, July 2000, pp. 1-6, XP001148413.					
	CD	Galletti, et al., "Controlled study of the effect of angiotensin converting enzyme inhibition versus calcium-entry blockade on insulin sensitivity in overweight hypertensive patients: trandolapril Italian Study (TRIS)," Journal of Hypertension, Vol. 17, No. 3, March 1999, pp. 439-445, XP008014000.					
	CE	Keilani, et al., "Selected aspects of ACE inhibitor therapy for patients with renal disease: impact on proteinuria, lipids and potassium," Journal of Clinical Pharmacology, United States, January 1995, Vol. 35, No. 1, pp. 87-97, XP008021110.					
	CF	Bakris, et al., "ACE inhibition or angiotensin receptor blockade: Impact on potassium in renal Failure," Kidney International, Vol. 58, No. 5, November 2000, pp. 2084-2092, XP001164193.					
	CG	Mutschler, "Arzneimittelwirkungen," WVG, Stuttgart, XP002232383, pp. 576, Col. 1, paragraph 1, Figures B4-27, Tables B4-29, pp. 579, Col. 1, Paragraph 3.					
	CH	Carlsson, et al., "Angiotensin II and the endocrine pancreas: effects on islet blood flow and insulin secretion in rats," Diabetologia, Germany, February 1998, Vol. 41, No. 2, pp. 127-133, XP001148412.					
	CI	Yusuf, et al., "Ramipril and the development of diabetes," Jama the Journal of the American Medical Association, Chicago, Illinois, Vol. 286, No. 15, 17 October 2001, pp. 1882-1885, XP008013945.					
	CJ	Yusuf, et al., "Effects of an angiotensin-converting-enzyme inhibitor, rampril, on cardiovascular events in high-risk patients," The Heart Outcomes Prevention Evaluation Study Investigators, The New England Journal of Medicine, January 2000, pp. 145-153, XP008013952.					
	CK	A copy of the International Search Report dated 10 August 2003 issued in corresponding international application no.: PCT/US02/33213.					
<b>EXAMINER:</b>					<b>DATE:</b>		